ORIGINAL

IN THE COURT OF COMMON PLEAS
HAMILTON COUNTY, OHIO
CIVIL DIVISION

SCOTT DANIEL
249 Ward Avenue
Bellevue, Kentucky 41073

Plaintiff,

v.

ABUBAKAR ATIQ DURRANI, M.D.
6905 BURLINGTON PIKE
FLORENCE, KY 41042
(Serve via Certified Mail) REGULAR MAIL WAIVER

And

CHILDREN'S HOSPITAL MEDICAL CENTER
3333 BURNET AVENUE
CINCINNATI, OH 45229
REGULAR MAIL WAIVER
Serve: Frank C. Woodside III
1900 Chemed Center
255 E. Fifth Street
Cincinnati, OH 45202
(Serve via Certified mail)

Defendants.

Case No. A 1 4 0 0 5 7 7

Judge

COMPLAINT
& JURY DEMAND

D105074304 INI

FILED
2014 JAN 31 P 1:30
CLERK OF COURTS
HAMILTON COUNTY, OH

Comes now Plaintiff, Scott Daniel, and files this Complaint and jury demand, and states as follows:

FACTUAL ALLEGATIONS OF PLAINTIFF

1. At all times relevant, Plaintiff, Scott Daniel (hereinafter "Plaintiff" or "Mr. Daniel"), was a resident of and domiciled in the State of Ohio.

2. At all times relevant, Defendant Dr. Abubakar Atiq Durrani (hereinafter "Dr. Durrani") was licensed to and did in fact practice medicine in the State of Ohio.

3. At all times relevant herein, Children's Hospital Medical Center (hereinafter "Children's Hospital") held itself out to the public, and specifically to Plaintiff, as a hospital providing competent and qualified medical and nursing services, care, and treatment by and through its physicians, physicians in training, residents, nurses, agents, ostensible agents, servants and/or employees.

4. The amount in controversy exceeds the jurisdictional threshold of this Court.

5. The subject matter of the Complaint arises out of medical treatment by the Defendants in Hamilton County, Ohio. This Court is thus the proper venue to grant Plaintiff the relief it seeks.

6. Mr. Daniel was diagnosed with scoliosis, fibromyalgia, and pectus carinatum as a young adult. In 2006, when Mr. Daniel was about 29 years old, he was referred to Dr. Durrani for back pain related to scoliosis.

7. Mr. Daniel met with Dr. Durrani at his Children's Hospital office several times and Dr. Durrani recommended surgery each time, telling Mr. Daniel that he could relieve him of all his pain.

8. In June, 2007, Dr. Durrani performed a segmental spinal fixation on Mr. Daniel to correct his scoliosis and kyphosis.

9. Upon information and belief, Dr. Durrani used either Infuse/ BMP-2 or PureGen

in Plaintiff's surgery, without Plantiff's knowledge or consent, causing Plaintiff harm.

10. After Mr. Daniel was released from Children's Hospital, he continued follow-up care with Dr. Durrani.

11. Mr. Daniel told Dr. Durrani the pain was much worse after the surgery than it had ever been before the surgery. Dr. Durrani referred him to physical therapy. Dr. Durrani told him the muscles needed to repair themselves and to give it time.

12. After time and physical therapy, Mr. Daniel again followed up with Dr. Durrani about his unbearable pain following the surgery. Dr. Durrani prescribed pain medicine and Mr. Daniel now is unable to function without the medication. Mr. Daniel also has anxiety and depression as a direct result of the physical pain incurred from surgery.

13. The procedures performed by Dr. Durrani were improperly performed and as a result, Mr. Daniel has incurred damages.

INFUSE/BMP-2

14. Dr. Durrani oftentimes used BMP-2 "off-label" when performing surgeries.

15. BMP-2 is manufactured, marketed, sold and distributed by Medtronic under the trade name "Infuse."

16. Dr. Durrani is a consultant for Medtronic.

17. Defendants did not inform Plaintiff of Durrani's financial interest, conflicts of interest or consulting arrangement with Medtronic.

18. Medtronic, provided in writing to Dr. Durrani the approved uses for BMP-2, the substance also referred to as Infuse, which is a bone morphogenic protein, used as an artificial substitute for bone grafting in spine surgeries.

19. BMP-2 is not approved by the Food and Drug Administration for use in the cervical and thoracic spine.

20. BMP-2 is neither safe nor approved for use on children less than twenty one (21) years of age.

21. For use in spinal surgery, BMP-2/Infuse is approved by the FDA for a limited procedure, performed on a limited area of the spine, using specific components. Specifically, the FDA approved Infuse for one procedure of the spine: Anterior Lumbar Interbody Fusion ("ALIF" or "Anterior" approach); and only in one area of the spine: L4 to S1; and only when used in conjunction with FDA-Approved Components: LT-CAGE Lumbar Tapered Fusion Device Component ("LT-CAGE").

22. Use of Infuse in cervical or thoracic surgery, or use through the back (posterior), or side (lateral), or on areas of the spine outside of the L4-S1 region (e.g., the cervical spine), or using components other than or in addition to the LT-CAGE is not approved by the FDA, and thus such procedures and/or use of non-FDA approved componentry is termed "off-label."

23. When used off-label, Infuse frequently causes excessive or uncontrolled (also referred to as "ectopic" or "exuberant") bone growth on or around the spinal cord. When nerves are compressed by such excessive bone growth, a patient can experience, among other adverse events, intractable pain, paralysis, spasms, and cramps in limbs.

24. The product packaging for BMP-2/Infuse indicates it causes an increased risk of cancer four (4) times greater than other bone graft alternatives.

25. Dr. Durrani and Children's Hospital personnel did not disclose to Plaintiff their intent to use BMP-2/Infuse, and further, did not disclose their intent to use BMP-2/Infuse in a way not approved by the FDA.

26. Dr. Durrani used BMP-2 in Plaintiff in manners not approved by Medtronic or the FDA.

27. Plaintiff was not informed by Dr. Durrani that Dr. Durrani used Infuse/BMP-2 in his surgery.

28. Plaintiff would not have allowed BMP-2 to be used by Dr. Durrani in his surgery(ies) in a manner that was not approved by the FDA or Medtronic, Infuse/BMP-2's manufacturer.

29. Plaintiff would not have consented to the use of BMP-2 in his body if informed of the risks by Dr. Durrani, or any Children's Hospital personnel.

30. The written informed consent of Dr. Durrani signed by Plaintiff lacked the disclosure of Infuse/BMP-2's use in his procedure(s).

31. Plaintiff never received a verbal disclosure of Infuse/BMP-2 from Dr. Durrani, or any Children's Hospital personnel.

32. Medtronic specifically required Infuse/BMP-2 only be used in "skeletally mature patients" with degenerative disc disease.

33. Medtronic required at least six (6) months of non-operative treatment prior to use of Infuse/BMP-2.

34. Dr. Durrani regularly used Infuse/BMP-2 without this six (6) month non-operative treatment.

35. Medtronic required BMP-2 always be used in conjunction with a metal LT cage.

36. Dr. Durrani regularly used BMP-2 without a proper LT cage in his surgeries.

DR. DURRANI COUNTS:

COUNT I: NEGLIGENCE

37. Defendant Dr. Durrani owed his patient, Plaintiff, the duty to exercise the degree of skill, care, and diligence an ordinarily prudent health care provider would have exercised under like or similar circumstances.

38. Defendant Dr. Durrani breached his duty by failing to exercise the requisite degree of skill, care and diligence that an ordinarily prudent health care provider would have exercised under same or similar circumstances through, among other things, negligent diagnosis, medical mismanagement and mistreatment of Plaintiff, including but not limited to improper selection for surgery, improper performance of the surgery, and improper follow-up care addressing a patient's concerns.

39. As a direct and proximate result of the aforementioned negligence and deviation from the standard of care on the part of the Defendant Dr. Durrani, Plaintiff sustained severe and grievous injuries, prolonged pain and suffering, emotional distress, humiliation, discomfort, loss of enjoyment of life, and loss of ability to perform usual and customary activities and incurred substantial medical expenses and treatment.

COUNT II: BATTERY

40. Dr. Durrani committed battery against Plaintiff by performing a surgery that was unnecessary, contraindicated for Plaintiff's medical condition, and for which he did not properly obtain informed consent, inter alia, by using BMP-2, PureGen and/or Baxano in ways and for surgeries not approved by the FDA and medical community, and by the failure to provide this information to Plaintiff.

41. Plaintiff would not have agreed to the surgeries if they knew the surgery(ies) was/were unnecessary, not approved by the FDA, and not indicated.

42. As a direct and proximate result of the aforementioned battery by Dr. Durrani, Plaintiff sustained severe and grievous injuries, prolonged pain and suffering, emotional distress, humiliation, discomfort, loss of enjoyment of life, loss of the ability to perform usual and customary activities, and incurred substantial medical expenses and treatment.

COUNT III: LACK OF INFORMED CONSENT

43. The informed consent forms from Dr. Durrani which they required Plaintiff to sign failed to fully cover all the information necessary and required for the procedures and surgical procedures performed by Dr. Durrani. Dr. Durrani required an informed consent release.

44. In addition, no one verbally informed Plaintiff of the information and risks required for informed consent at the time of or before Plaintiff's surgery(ies).

45. Dr. Durrani failed to inform Plaintiff of material risks and dangers inherent or potentially involved with his surgery(ies) and procedures.

46. Plaintiff subsequently developed severe and grievous injuries as a direct and proximate result of lack of informed consent.

47. Had Plaintiff been appropriately informed of the need or lack of need for surgery and other procedures and the risks of the procedures, Plaintiff would not have undergone the surgery or procedures.

COUNT IV: INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

48. Dr. Durrani's conduct as described above was intentional and reckless.

49. It is outrageous and offends against the generally accepted standards of morality.

50. It was the proximate and actual cause of Plaintiff's psychological injuries, emotional injuries, mental anguish, suffering, and distress.

51. Plaintiff suffered severe distress and anguish so serious and of a nature that no reasonable man or woman would be expected to endure.

COUNT V: FRAUD

52. Dr. Durrani made material, false representations to Plaintiff and his insurance company related to Plaintiff's treatment including: stating the surgery was necessary, that Dr. Durrani "could fix" Plaintiff, that more conservative treatment was unnecessary and futile, that the surgery would be simple or was "no big deal", that Plaintiff would be walking normally within days after each surgery, that the procedures were medically necessary and accurately reported on the billing to the insurance company, that the surgery was successful, and that Plaintiff was medically stable and ready to be discharged.

53. Dr. Durrani also concealed the potential use of Infuse/BMP-2 and/or Puregen in Plaintiff's surgery when he had a duty to disclose to Plaintiff his planned use of the same.

54. These misrepresentations and/or concealments were material to Plaintiff because they directly induced Plaintiff to undergo his surgery(ies).

55. Dr. Durrani knew or should have known such representations were false, and/or made the misrepresentations with utter disregard and recklessness as to their truth that knowledge of their falsity may be inferred.

56. Dr. Durrani made the misrepresentations both before, during and after the surgery(ies) with the intent of misleading Plaintiff and his insurance company into relying upon them. Specifically, the misrepresentations were made to induce payment by

the insurance company, without which Dr. Durrani would not have performed the surgery(ies), and to induce Plaintiff to undergo the surgery(ies) without regard to medical necessity and only for the purpose of receiving payment.

57. The misrepresentations and/or concealments were made during Plaintiff's office visits at Dr. Durrani's offices and/or at Children's Hospital.

58. Plaintiff justifiably relied on the misrepresentations because a patient has a right to trust his doctor and that the facility is overseeing the doctor to ensure the patients of that doctor can trust the facility.

59. As a direct and proximate result of the aforementioned fraud, Plaintiff did undergo surgery(ies) which were paid for in whole or in part by his insurance company, and suffered severe and grievous injuries, paralysis, new and different pain, prolonged pain and suffering, emotional distress, humiliation, discomfort, loss of enjoyment of life, loss of ability to perform usual and customary activities, and incurred substantial medical expenses and treatment.

COUNT VI: SPOLIATION OF EVIDENCE

60. Dr. Durrani willfully altered, destroyed, delayed, hid, modified and/or spoiled ("spoiled") Plaintiff's records, billing records, paperwork and related evidence.

61. Dr. Durrani spoiled evidence with knowledge that there was pending or probable litigation involving Plaintiff.

62. Dr. Durrani's conduct was designed to disrupt Plaintiff's potential and/or actual case, and did in fact and proximately cause disruption, damages and harm to Plaintiff.

CHILDREN'S HOSPITAL COUNTS:

COUNT I: VICARIOUS LIABILITY

63. At all times relevant, Defendant Dr. Durrani was an agent, and/or employee of Children's Hospital..

64. Defendant Dr. Durrani was performing within the scope of his employment with Children's Hospital during the care and treatment of Plaintiff.

65. Defendant Children's Hospital is responsible for harm caused by acts of its employees for conduct that was within the scope of employment under the theory of respondeat superior.

66. Defendant Children's Hospital is vicariously liable for the acts of Defendant Dr. Durrani alleged in this Complaint including all of the counts asserted against Dr. Durrani directly.

67. As a direct and proximate result of Defendant Children's Hospital's acts and omissions, Plaintiff sustained severe and grievous injuries, prolonged pain and suffering, emotional distress, humiliation, discomfort, loss of enjoyment of life, and loss of ability to perform usual and customary activities and incurred substantial medical expenses and treatment.

COUNT II: NEGLIGENT HIRING, RETENTION, SUPERVISION & CREDENTIALING

68. Children's Hospital provided Dr. Durrani, inter alia, financial support, control, medical facilities, billing and insurance payment support, staff support, medicines, and tangible items for use on patients.

69. Children's Hospital and Dr. Durrani participated in experiments using BMP-2 and/or Puregen bone graft on patients, including Plaintiff, without obtaining proper informed consent thereby causing harm to Plaintiff.

70. Children's Hospital breached its duty to Plaintiff, inter alia, by not controlling the actions of Dr. Durrani and the doctors, nurses, staff, and those with privileges, during the medical treatment of Plaintiff.

71. The Safe Medical Device Act required entities such as Children's Hospital to report serious injuries, serious illnesses, and deaths related to failed medical devices to the FDA and the manufacturer; this was never done.

72. Such disregard for and violations of federal law represents strong evidence that Children's Hospital negligently hired, retained, supervised and granted privileges to Dr. Durrani.

73. As a direct and proximate result of the acts and omissions herein described, including but not limited to failure to properly supervise medical treatment by Dr. Durrani, Plaintiff sustained severe and grievous injuries, prolonged pain and suffering, emotional distress, humiliation, discomfort, loss of enjoyment of life, loss of the ability to perform usual and customary activities, and incurred substantial medical expenses and treatment.

COUNT III: SPOLIATION OF EVIDENCE

74. Children's Hospital, through its agents and employees, willfully altered, destroyed, delayed, hid, modified and/or spoiled ("spoiled") Plaintiff's records, billing records, paperwork and related evidence.

75. Children's Hospital, through its agents and employees, spoiled evidence with knowledge that there was pending or probable litigation involving Plaintiff.

76. Children's Hospital's conduct was designed to disrupt Plaintiff's potential and/or actual case, and did in fact and proximately cause disruption, damages and harm to Plaintiff.

COUNT IV: FRAUD

77. Children's Hospital also either concealed from Plaintiff that Infuse/BMP-2 or Puregen would be used in Plaintiff's surgery, or misrepresented to Plaintiff the nature and necessity of the surgery and the particular risks that were involved therein.

78. Children's Hospital's concealments and misrepresentations regarding Infuse/BMP-2 or Puregen and the nature, necessity, and risks of Plaintiff's surgery/ies were material facts.

79. Because of its superior position and professional role as a medical service provider, Children's Hospital had a duty to disclose these material facts to Plaintiff and a duty to refrain from misrepresenting such material facts to Plaintiff.

80. Children's Hospital intentionally concealed and/or misrepresented said material facts with the intent to defraud Plaintiff in order to induce Plaintiff to undergo the surgery, and thereby profited from the surgeries and procedures Dr. Durrani performed on Plaintiff at Children's Hospital.

81. Plaintiff was unaware that Infuse/BMP-2 or Puregen would be used in Plaintiff's surgery and therefore, was unaware of the health risks of Infuse/BMP-2 or Puregen's use in Plaintiff's spine.

82. Had Plaintiff known before Plaintiff's surgery/ies that Infuse/BMP-2 or Puregen would be used in Plaintiff's spine and informed of the specific, harmful risks flowing

therefrom, Plaintiff would not have undergone the surgery/ies with Dr. Durrani at Children's Hospital.

83. As a direct and proximate result of Children's Hospital's concealments and/or misrepresentations regarding Infuse/BMP-2 or Puregen, and the nature and necessity of the surgery/ies performed by Dr. Durrani at Children's Hospital, Plaintiff sustained, inter alia, economic, and non-economic (including physical, emotional) damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests and seeks justice in the form and procedure of a jury, verdict and judgment against Defendants on all claims for the following damages:

1. Past medical bills;
2. Future medical bills;
3. Lost income and benefits;
4. Lost future income and benefits;
5. Loss of ability to earn income;
6. Past pain and suffering;
7. Future pain and suffering;
8. Plaintiff seeks a finding that his injuries are catastrophic under Ohio Rev. Code §2315.18;
9. All incidental costs and expenses incurred as a result of his injuries;
10. The damages to his credit as a result of his injuries;
11. Punitive damages;
12. Costs;

13. Attorneys' fees;

14. Interest;

15. All property loss;

16. All other relief to which they are entitled including O.R.C. 1345.01

Based upon 1-17 itemization of damages, the damages sought exceed the minimum jurisdictional amount of this Court and Plaintiff seeks in excess of $25,000.

Respectfully Submitted,

(0091099) for Debra A. Nelson

/s/ Debra A. Nelson

Debra Nelson (# 0077538)
Attorney for Plaintiff
637 W. 7th Street
Cincinnati, OH 45203
513-729-1999 Fax: 513-381-4084
dnelson@ericdeters.com

JURY DEMAND

Plaintiff makes a demand for a jury under all claims.

(0091099) for Debra A. Nelson

/s/ Debra A. Nelson

Debra Nelson